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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,710	02/24/2004	Mark L. Nelson	PAZ-025CPCN	3651

959 7590 05/25/2006

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EXAMINER	
FREISTEIN, ANDREW B	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,710	NELSON ET AL.	
	Examiner	Art Unit	
	Andrew B. Freistein	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21,23-80 and 82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11-13,16,18,19,27,63 and 82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 5/4/2006 has been entered. Claims 1-19, 21, 23-80 and 82 are pending. Claims 20, 22, 81 and 83-102 were cancelled.

Claim Rejections - 35 USC § 102

(1) Claims 1-5, 11-13, 16, 18-20, 22 and 82 were rejected under 35 U.S.C. 102(b) as being anticipated by Barden et al, "'Glycylcyclines' 3. 9-Aminodoxycyclinecarboxamides," J. Med. Chem., 37(20), 3205-11 (1994). As a result of the amendment filed 5/4/2006, the rejection is withdrawn.

(2) Claims 1, 11-13, 16, 19, 20-22 and 82 were rejected under 35 U.S.C. 102(b) as being anticipated by Sum et al., US Pat. No. 5,430,162. As a result of the amendment filed 5/4/2006, the rejection is withdrawn.

(3) Claims 1-6, 11-13, 16, 20-22 and 82 were rejected under 35 U.S.C. 102(b) as being anticipated by Hlauka et al., US Pat. No. 5,494,903. As a result of the amendment filed 5/4/2006, the rejection is withdrawn.

Claim Rejections – Double Patenting

(1) Claims 1-10, 41-55, 69-76, and 82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26, 32 and 51-81 of U.S. Pat. No. 6,818,634 (the '634 patent). This provisional rejection is maintained. Upon allowance, Applicant agreed to filed a terminal disclaimer to obviate this rejection.

Claim Rejections - 35 USC § 112

Claims 1, 5, 9, 19, 27-28, 63 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) The rejection of the term "prodrug moiety" is withdrawn.

(2) The rejection of the term "derivative" is maintained. Applicant traverses the rejection arguing that, "a skilled artisan would have been able to use Table 1 at page 6 as well as the description to determine appropriate tetracycline derivates." Although examples of tetracycline derivates are shown in the table 1, derivatives is still not specifically defined. Moreover, exemplification is not an explicit definition. The specification must set forth the definition explicitly and clearly, with reasonable clarity, deliberateness and precision. Teleflex Inc. v. Ficosa North Am Corp., 63 USPQ2d 1374, (Fed. Cir. 2002), Rexnord Corp. v. Laitram Corp., 60 USPQ2d 1854 (Fed. Cir. 2001). Here, the precise derivative that applicant **claims** as his invention is unknown. Thus, the rejection is maintained and made FINAL.

(3) The rejection of the term "multicyclic" is maintained. Applicant traverses the rejection asserting that, "a skilled artisan in possession of the specification would have been able to reasonably understand that the term "multicyclic" denotes being related to a multicycle, which is defined in the specification at page 23, lines 24-26..." Examiner respectfully disagrees with Applicant's assumption. On page 23, line 36, the specification states, "Examples of "multicyclic" moieties include steroids, such as, for example, cholesterol." A skilled artisan is thus lead to believe that a multicylic is large

functional group such as cholesterol, rather than naphthalene, for example. Absent a clear definition, "multicyclic" is ambiguous. Applicant must specifically point out and distinctly claim the compound he regards as his invention. The rejection is maintained and made FINAL.

(4) The rejection of the term "steroidyl" was overcome by the amendment of claim 28 filed 5/4/2006. As a result, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

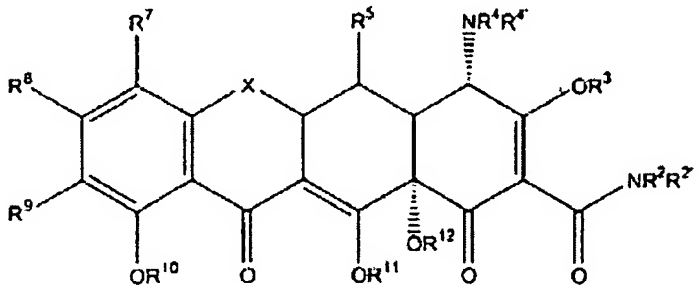
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 11-13, 16, 18-19 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barden et al, "'Glycylcyclines' 3. 9-Aminodoxycyclinecarboxamides," J. Med. Chem., 37(20), 3205-11 (1994).

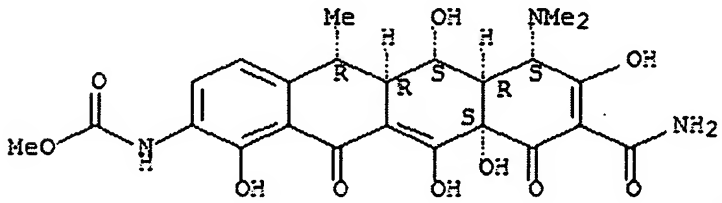
The instant application claims a compound of formula (I),



, wherein X is $CR^{6'}R^{6}$; R^2, $R^{2'}$, R^3, R^6, R^7, R^8, R^{9c}, R^{10}, R^{11} and R^{12} are each H; R^4, $R^{4'}$ and $R^{6'}$ are each alkyl; R^5 is hydroxyl; R^9 is $NR^{9c}C(=Z')ZR^{9a}$; Z is O; Z' is O; and R^{9a} is ethyl.

Determining the Scope and Content of the Prior Art

Barden et al. disclose the compound and pharmaceutical composition comprising the compound comprising the compound



(see, p. 3206, Scheme 2[a], compound 12).

Ascertaining the Difference Between the Prior Art and the Instant Application

The instant application claims a compound of formula (I), wherein R^9 is $NR^{9c}C(=Z')ZR^{9a}$; Z is O; Z' is O; and R^{9a} is ethyl. The prior art discloses a compound wherein the "R^{9a}" variable is methyl.

Finding Prima Facie Obviousness

To those skilled in the chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties

of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious, because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in pharmaceutical compositions. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

NO CLAIM IS ALLOWED.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein
Patent Examiner, AU 1626

for Shameem

Joseph K. McKane
Supervisory Patent Examiner, AU 1626
Date: May 19, 2006